

KO 83463

MAR 13 2009

510(k) Summary for

Dimension Vista® B2MIC Flex® reagent cartridge

Dimension Vista® Protein 1 Calibrator

Dimension Vista® Protein 1 Control L and M

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Siemens Healthcare Diagnostics Products

Emil-von-Behring Str. 76

35041 Marburg, Germany

Contact Information: Siemens Healthcare Diagnostics.

500 GBC Drive, M/S 514

Newark, Delaware 19702

Attn: Anna Marie Kathleen Ennis

Tel: 302-632-9352

Fax: 302-631-6299

Preparation date: February 4, 2009

**2. Device Name:**

Dimension Vista® B2MIC Flex® reagent cartridge

Dimension Vista® PROT 1 CAL

Dimension Vista® PROT 1 CON L and M

Classification: Class II; Class II; Class I

Product Code: JZG, JIX, JJY

Panel: Immunology (82) and Clinical Chemistry (75)

**3. Identification of the Legally Marketed Devices:**

Siemens N Latex  $\beta_2$ - microglobulin – K002731

N Protein Standard SL - K052788

N/T Protein Controls SL - K052788

#### **4. Device Descriptions:**

##### **Dimension Vista® B2MIC Flex® reagent cartridge**

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

##### **Dimension Vista® Protein 1 Calibrator**

Protein 1 Calibrator is a multi-analyte, liquid human serum based product containing:  $\alpha_1$ -acid glycoprotein,  $\alpha_1$ -antitrypsin,  $\alpha_2$ -macroglobulin,  $\beta_2$ -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, hemopexin, immunoglobulin A, immunoglobulin E, immunoglobulin G, immunoglobulin G subclass 1, immunoglobulin G subclass 2, immunoglobulin G subclass 3, immunoglobulin G subclass 4, immunoglobulin M, prealbumin, retinol binding protein, homocysteine, soluble transferrin receptor and transferrin.

##### **Dimension Vista® Protein 1 Control L**

Protein 1 Control L is a multi-analyte, low level liquid human serum based product containing :

$\alpha_1$ -acid glycoprotein,  $\alpha_1$ -antitrypsin,  $\alpha_2$ -macroglobulin,  $\beta_2$ -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, hemopexin, immunoglobulin E, immunoglobulin A, immunoglobulin G, immunoglobulin G Subclass , immunoglobulin G subclass 2, immunoglobulin G subclass 3, immunoglobulin G subclass 4, immunoglobulin M, prealbumin, retinol binding protein, homocysteine, soluble transferrin receptor and transferrin

##### **Dimension Vista® Protein 1 Control M**

Protein 1 Control M is a multi-analyte, mid level, liquid human serum based product containing:  $\alpha_1$ -acid glycoprotein,  $\alpha_1$ -antitrypsin,  $\alpha_2$ -macroglobulin,  $\beta_2$ -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, hemopexin, immunoglobulin A, immunoglobulin E, immunoglobulin G, immunoglobulin G subclass 1, immunoglobulin G subclass 2, immunoglobulin G subclass 3, immunoglobulin G subclass 4, immunoglobulin M, prealbumin, retinol binding protein, homocysteine, soluble transferrin receptor, and transferrin.

#### **5. Device Intended Uses**

##### **Dimension Vista® B2MIC Flex® reagent cartridge:**

The B2MU method is an *in vitro* diagnostic test for the quantitative measurement of  $\beta_2$ -microglobulin in human serum, heparinized plasma, EDTA plasma and urine using the B2MIC Flex® reagent cartridge on the Dimension Vista® Systems. Measurement of  $\beta_2$ -microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.

##### **Dimension Vista® PROT 1 CAL:**

PROT1 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® Systems for:  $\alpha_1$ -Acid Glycoprotein (A1AG),  $\alpha_1$ -Antitrypsin (A1AT),  $\alpha_2$ -macroglobulin (A2MAC),  $\beta_2$ -Microglobulin (B2MIC, B2MU\*\*), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Hemopexin (HPX), Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin E (IGE), Immunoglobulin G (IGG, IGG-C\*, ICC-U\*\*), Immunoglobulin G subclass 1 (IGG1), Immunoglobulin G subclass 2 (IGG2), Immunoglobulin G subclass 3 (IGG3), Immunoglobulin G subclass 4 (IGG4), Immunoglobulin M (IGM), Prealbumin (PREALB), Retinol Binding Protein (RBP), soluble Transferrin Receptor (STFR), Transferrin (TRF)

\*For cerebrospinal fluid

\*\* For urine

#### **Dimension Vista® Protein 1 Control L**

PROT1 CON L is an assayed, low level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® Systems in the quantitative determination of:  $\alpha_1$ -Acid Glycoprotein (A1AG),  $\alpha_1$ -Antitrypsin (A1AT),  $\alpha_2$ -Macroglobulin (A2MAC),  $\beta_2$ -Microglobulin (B2MIC-U\*\*), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Hemopexin (HPX), Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin E (IGE), Immunoglobulin G (IGG), Immunoglobulin G subclass 1 (IGG1), Immunoglobulin G subclass 2 (IGG2), Immunoglobulin G subclass 3 (IGG3), Immunoglobulin G subclass 4 (IGG4), Immunoglobulin M (IGM), Prealbumin (PREALB), Retinol Binding Protein (RBP), specialty Albumin (sALB\*), soluble Transferrin Receptor (STFR) and Transferrin (TRF).

\*For serum and plasma

\*\* For Urine

#### **Dimension Vista® Protein 1 Control M**

PROT1 CON M is an assayed, mid-level, intralaboratory quality controls for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:  $\alpha_1$ -Acid Glycoprotein (A1AG),  $\alpha_1$ -Antitrypsin (A1AT),  $\alpha_2$ -Macroglobulin (A2MAC),  $\beta_2$ -Microglobulin (B2MIC\*, B2MIC-U\*\*), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Hemopexin (HPX), Homocysteine (HCYS), Immunoglobulin A (IGA), Immunoglobulin E (IGE), Immunoglobulin G (IGG), Immunoglobulin G subclass 1 (IGG1), Immunoglobulin G subclass 2 (IGG2), Immunoglobulin G subclass 3 (IGG3), Immunoglobulin G subclass 4 (IGG4), Immunoglobulin M (IGM), Prealbumin (PREALB), Retinol Binding Protein (RBP), specialty Albumin (sALB\*), soluble Transferrin Receptor (STFR) and Transferrin (TRF).

\*For serum and plasma

\*\* For urine

#### **6. Medical device to which equivalence is claimed and comparison information:**

The Dimension Vista® B2MIC Flex® reagent cartridge, Dimension Vista® PROT 1 CAL and Dimension Vista® PROT 1 CON L and M, are substantially equivalent to the Siemens N Latex  $\beta_2$ -microglobulin assay (K002731), N/T Protein Standard SL (K052788) and N Protein Controls SL (K052788). The Dimension Vista® B2MIC assay, like Siemens N Latex  $\beta_2$ -microglobulin assay is an *in vitro* diagnostic test for the quantitative measurement of  $\beta_2$ -microglobulin in human serum, plasma and urine.

#### **7. Device Performance Characteristics:**

### **Method Comparison Study**

The Dimension Vista® B2MU assay was compared to the N Latex to Human  $\beta_2$ -microglobulin on the BN ProSpec® System by evaluating urine samples with concentrations ranging from 0.022 – 0.553 mg/dL (0.223 – 5.53mg/L). Regression analysis of these results yielded the following equation:

Comparative Method	Slope	Intercept mg/dL (mg/L)	Correlation Coefficient	n
$\beta_2$ -microglobulin on BN Prospec®	0.952	-0.0008 (-0.008)	0.988	82



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Seimens Healthcare Diagnostics Inc.  
c/o Ms. Anna Marie Kathleen Ennis  
Senior Regulatory Affairs and Compliance Specialist  
500 GBC Drive  
P.O. Box 601  
Newark, DE 19714-6101 US

MAR 13 2009

Re: k083463

Trade/Device Name: Dimension Vista® B2MIC Flex® reagent cartridge  
Dimension Vista® Protein 1 Calibrator  
Dimension Vista® Protein 1 Control L  
Dimension Vista® Protein 1 Control M

Regulation Number: 21 CFR 866.5630

Regulation Name: Beta-2-microglobulin immunological test system

Regulatory Class: Class II

Product Code: JZG, JIX, JJY

Dated: February 4, 2009

Received: February 5, 2009

Dear Ms. Ennis,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Maria M. Chan".

Maria M. Chan, Ph.D.  
Director  
Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and  
Safety  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K083463

Device Name: Dimension Vista® B2MIC Flex Reagent Cartridge

Indication for Use:

The B2MIC method is an *in vitro* diagnostic test for the quantitative measurement of  $\beta_2$ -microglobulin in human serum, heparinized plasma, EDTA plasma and urine on the Dimension Vista® System. Measurements of beta-2-microglobulin, aid in the diagnosis of active rheumatoid arthritis and kidney disease.

Prescription Use   X  

And/Or

Over the Counter Use

(21 CFR Part 801 Subpart D)  
Subpart C)

(21 CFR Part 801

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety  
(OIVD)

Maria M Chen

Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K083463

## Indications for Use

510(k) Number (if known): K083463

Device Name: **Dimension Vista® PROT 1 CON L**

### Indications For Use:

PROT1 CON L is an assayed, low-level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin G (IGG)
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin G Subclass 1 (IGG1)
$\alpha_2$ -Macroglobulin (A2MAC)	Immunoglobulin G Subclass 2 (IGG2)
$\beta_2$ -Microglobulin (B2MIC, B2MU**)	Immunoglobulin G Subclass 3 (IGG3)
C3 Complement (C3)	Immunoglobulin G Subclass 4 (IGG4)
C4 Complement (C4)	Immunoglobulin M (IGM)
Ceruloplasmin (CER)	Prealbumin (PREALB)
Haptoglobin (HAPT)	Retinol binding Protein (RBP)
Hemopexin (HPX)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	specialty Albumin (sALB*)
Immunoglobulin A (IGA)	Transferrin (TRF)
Immunoglobulin E (IGE)	

\* For serum and plasma

\*\* For urine

Prescription Use   X   AND/OR Over-The-Counter-Use         
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K083463



## Indications for Use

510(k) Number (if known): K083463

Device Name: **Dimension Vista<sup>®</sup> PROT 1 CAL**

### Indications For Use:

#### **Dimension Vista<sup>®</sup> PROT 1 CAL:**

PROT1 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista<sup>®</sup> System for:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin E (IGE)
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin G (IGG, IGG-C*, IGG-U**)
$\alpha_2$ - Macroglobulin (A2MAC)	Immunoglobulin G Subclass 1 (IGG1)
$\beta_2$ -Microglobulin (B2MIC, B2MU**)	Immunoglobulin G Subclass 2 (IGG2)
C3 Complement (C3)	Immunoglobulin G Subclass 3 (IGG3)
C4 Complement (C4)	Immunoglobulin G Subclass 4 (IGG4)
Ceruloplasmin (CER)	Immunoglobulin M (IGM)
Haptoglobin (HAPT)	Prealbumin (PREALB)
Hemopexin (HPX)	Retinol binding Protein (RBP)
Homocysteine (HCYS)	soluble Transferrin Receptor (STFR)
Immunoglobulin A (IGA)	Transferrin (TRF)

\* For cerebrospinal fluid (CSF)

\* For Urine

Prescription Use   X   AND/OR Over-The-Counter-Use         
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K083463

## Indications for Use

510(k) Number (if known): *K083463*

Device Name: **Dimension Vista® PROT 1 CON M**

### Indications For Use:

PROT1 CON M is an assayed, mid-level, intralaboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin G (IGG)
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin G Subclass 1 (IGG1)
$\alpha_2$ -Macroglobulin (A2MAC)	Immunoglobulin G Subclass 2 (IGG2)
$\beta_2$ -Microglobulin (B2MIC, B2MU**)	Immunoglobulin G Subclass 3 (IGG3)
C3 Complement (C3)	Immunoglobulin G Subclass 4 (IGG4)
C4 Complement (C4)	Immunoglobulin M (IGM)
Ceruloplasmin (CER)	Prealbumin (PREALB)
Haptoglobin (HAPT)	Retinol binding Protein (RBP)
Hemopexin (HPX)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	specialty Albumin (sALB*)
Immunoglobulin A (IGA)	Transferrin (TRF)
Immunoglobulin E (IGE)	

\* For serum and plasma

\*\* For urine

Prescription Use   X   AND/OR Over-The-Counter-Use         
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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